



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,527	11/02/2006	Andrew James Brown	Pb60728USW	2346

23347 7590 07/03/2008
GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B482
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

RICCI, CRAIG D

ART UNIT	PAPER NUMBER
----------	--------------

4161

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

07/03/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
LAURA.M.MCCULLEN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

Office Action Summary	Application No. 10/597,527	Applicant(s) BROWN ET AL.	
	Examiner CRAIG RICCI	Art Unit 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 6/09/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/28/06, 1/23/07, 6/09/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1 and 4-7 are pending. Claim 7 is currently pending and the subject of this Office Action. Claims 1 and 4-6 are withdrawn. Claims 2-3 are cancelled. This is the first Office Action on the merits of the claims.

Information Disclosure Statement

2. All references have been considered except as lined through. The Huffman reference was not considered because the reference is incomplete.

Priority

3. The earliest effective filing date afforded the instantly claimed invention has been determined to be 02/01/2005 as to claim 7.

4. Acknowledgment is made of Applicant's claim for foreign priority pursuant to 35 U.S.C. 119(a) and 365(b) based on a prior application filed in the United Kingdom on 02/03/2004. The certified copy has been filed in parent Application No. PCT/GB05/00348, filed on 02/01/2005 and received in this national stage filing.

Election/Restrictions

5. Applicant's election without traverse of Group I (claim 7) drawn to a composition in the reply filed on 6/09/2008 is acknowledged.

6. The requirement is thus deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claim 7 rejected under 35 U.S.C. 102(b) as being anticipated by *Kozlowski et al* (WO 02/062750).**

9. Instant claim 7 recites a "pharmaceutical composition comprising one or more CB2 modulators and one or more PDE4 inhibitors adapted for use in a human or veterinary medicine" (claim 7). *Kozlowski et al* teach "cannabinoid receptor ligands and, more particularly... compounds that bind to cannabinoid (CB2) receptors" (Page 1, Paragraph 1). Furthermore, *Kozlowski et al* teach that "Additionally, a compound of the present invention may be co-administered or used in combination with... PDE4 inhibitors" (Pages 3-4). Moreover, *Kozlowski et al* teach the combination in the treatment of various medical conditions suffered by humans. Accordingly, *Kozlowski et al* teach a pharmaceutical composition comprising one or more CB2 modulators and one or more PDE4 inhibitors for use in human medicine. Since each element of instant claim 7 is anticipated by *Kozlowski et al*, claim 7 is rejected.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1638

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over**

***Iwamura et al* (J Pharmacol Exp Ther 296(2):420-425, 2001) in view of *Van der Mey et al* (J Med Chem 45:2520-2525, 2002).**

13. As discussed above, instant claim 7 is drawn to compositions comprising one or more CB2 modulators and one or more PDE4 inhibitors. *Iwamura et al* teach the use of CB2 modulators in the treatment of inflammatory disorders. Specifically, *Iwamura et al* teach that “a CB2-selective inverse agonist, JTE-907, has an anti-inflammatory effect in vivo” (abstract). However, *Iwamura et al* do not teach the combination of a CB2-modulator with a PDE4 inhibitor.

14. *Van der Mey et al* teach the use of PDE4 inhibitors in the treatment of inflammatory disorders. Specifically, *Van der Mey et al* teach that selective PDE4 inhibitors “show high anti-inflammatory activities in vivo after oral application” and “are considered to be promising agents for the treatment of rheumatoid arthritis, asthma, and other inflammatory diseases” Page 2523, Column 2, Paragraph 3).

Art Unit: 1638

15. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the teachings of *Iwamura et al* and *Van der Mey et al*. *Iwamura et al* and *Van der Mey et al*. teach the use of CB2 modulators and PDE4 inhibitors, respectively, in the treatment of inflammatory conditions. As stated in MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626, F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Thus, it is prima facie obvious to combine one agent which is known to treat inflammatory disorders with another agent which is known to treat inflammatory disorders to form a third composition for the treatment of inflammatory disorders. Accordingly, claim 7 is obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571)270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 4161

/Ashwin Mehta/
Primary Examiner, Technology Center 1600